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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,850	01/07/2002	Jean C. Gan	5490E-000249	5507
27572	7590	11/19/2004	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C.			SCHAETZLE, KENNEDY	
P.O. BOX 828			ART UNIT	PAPER NUMBER
BLOOMFIELD HILLS, MI 48303			3762	
DATE MAILED: 11/19/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/041,850

Applicant(s)

GAN ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 3-5,7,8,11-13,15,16,18,20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,9,10,14,17 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/22/02, 11/7/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of the species involving the use of an AC generator for generating a sine wave and an intermittent electrical field (claims 1, 2, 6, 9, 10, 14, 17 and 19) in the reply filed on August 30, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 6, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Brighton et al. (Pat. No. 4,535,775).

Regarding claims 1 and 2, Brighton et al. disclose a treatment method comprising: providing an alternating signal generator (18) in electrical communication with first and second electrodes (12); disposing the first and second electrodes on a skin surface on opposing sides of a wound (see Fig. 1); and applying an electric field in the soft tissue by generating an electrical signal at a frequency within a range of 20 to 100 kHz and having a symmetrical waveform with an amplitude within a range of 0.1 to 20 volts peak-to-peak through said first and second electrodes (note col. 2, lines 30-38).

While the treatment of soft tissue wounds was considered, given the substantially similar stimulation parameters involved, the examiner considers the method of Brighton et al. to inherently assist in the healing of soft tissue wounds. Broken or fractured bone would necessarily be accompanied by soft tissue wounds as a result of the traumatic injury. Therefore, when one is disposing the electrodes on the skin as shown in Fig. 1,

one must necessarily dispose the electrodes on a skin surface on opposing sides of a soft tissue wound as well.

Regarding claim 6, note col. 2, lines 35-38.

The rejection of claims 17 and 19 parallels that of claims 1 and 2. The examiner considers an electric field to be inherently produced when the stimulation signal is applied between the two electrodes.

### ***Claim Rejections - 35 USC § 102/103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9, 10 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brighton et al. (Pat. No. 4,535,775).

6. Regarding claims 9 and 10, note the rejection of similar limitations in claims 1 and 2. Specifically concerning the issue of periodically reconfiguring the first and second electrodes about the soft tissue wound, Brighton et al. disclose that the electrodes need to be cleaned with fresh conductive jelly applied daily (col. 2, lines 45-58). The examiner considers such an act to constitute a periodic reconfiguration of the electrodes. In any event, one could argue that the cast itself must be periodically removed to permit examination during the course of treatment, with a new clean cast subsequently applied with new ports 13 drilled in to accommodate the electrodes. Any slight variance in port site location would concomitantly result in a change in electrode position, thus effectively representing a reconfiguration of the electrodes. Furthermore, it is the examiner's opinion that any one of ordinary skill in the medical treatment arts would have thought it obvious to purposefully reconfigure the electrodes if subsequent

follow-up examination indicated ineffective results with the current configuration (or the need to incorporate fringe tissue areas that were not adequately covered by stimulation with the first electrode configuration).

The rejection of claim 14 parallels the rejection of claim 6.

**Conclusion**

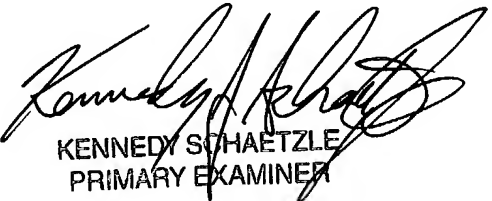
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-2954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272-2955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS  
November 17, 2004

  
KENNEDY SCHAETZLE  
PRIMARY EXAMINER